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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER MAEWALL, SNIGDEHA				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

## Application No.

10/724,826

## Applicant(s)

SIMONNET ET AL.

## Examiner

Snigdha Maewall

## Art Unit

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 25, 27-34 and 36-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25, 27-34 and 36-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Receipt of Applicants' amendments, remarks and amended claims filed on 12/21/10 is acknowledged.

Claims 1-24, 26 and 35 have been cancelled and claims 44-53 remain withdrawn.

Claims **25, 27-34 and 36-43** are being examined on the merits herein.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims **25, 27-34 and 36-43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (US 5,753,241), in view of Tabibi et al. (US 5,130,122) and further in view of Schwarz et al. (USP 6, 117,415) and Shukuzaki et al. (USP 5,266,321) and as evidenced by Halloran (USP 6,153,569).

Ribier et al. teach an **oil-in-water** nanoemulsion, in which the oil globules are less than 100 nm, and contain an amphiphilic lipid component (abstract). The amount of oil ranges from **5 to 30%** by weight with respect to the total weight of the emulsion (column 3, lines 16-18). The oil can be silicone oil, namely decamethylcyclopentasiloxane, which has a molecular weight of 370.78 (column 3, line

47). The oil can also be Jojoba oil, which contains 36 to 46 carbons, and has a molecular weight of at least 432 (column 5, example 1; and wikipedia.org). Jojoba oil makes up 50% of the oils having a molecular weight greater than 400 (column 5, example 1).

Ribier et al. teach ionic amphiphilic lipids in the nanoemulsions, which can be alkaline salts of dicetyl and dimyristyl phosphate, alkaline salts of cholesterol sulphate, alkaline salts of cholesterol phosphate, sodium salts of phosphatidic acid, phospholipids, or **alkylsulfonic derivatives** (columns 2, lines 57-65; and column 3, lines 1-3). The ionic amphiphilic lipids are from 2 to 10% by weight (column 3, line 13).

Ribier et al. also teach emulsions that contain additives to improve the **transparency** of the formulation, such as lower alcohols and are 5 to 20% by weight (column 3, lines 49-51, 53, and 62). Ribier et al. also teach the nanoemulsion for topical use such as a cosmetic or dermatopharmaceutical composition and for use on the eyes (column 4, lines 45-49). Since the nanoemulsion of Ribier et al. is for ophthalmic use (e.g. use on the eyes), it would be obvious that such a nanoemulsion contains an ophthalmic vehicle.

Ribier et al. do not teach nanoemulsions containing the surfactants herein and the turbidity of the nanoemulsion.

Tabibi et al. while teaching submicron emulsion of adsorptive oil teaches utilization of surfactants (column 6, lines 58-59 and 62). The adsorptive oil may be from vegetable oils, mineral oils, or animal oils (column 2, lines 33-35). The submicron emulsions are less than about 0.3 microns in diameter (column 4, lines 13-15). Tabibi et

al. do not specifically name surfactants however, it would be obvious that the surfactants of Tabibi et al. may include sucrose distearate as recited in claims 30 and 31 and other surfactants that are solids at a temperature of less than or equal to 45°C as the reference generically discloses addition of surfactants.

While Tabibi discloses addition of surfactants in microemulsions formulation, Tabibi does not specifically mention sucrose fatty acid ester as surfactant.

Schwarz et al. teaches a submicron emulsion comprising surfactant such as sugar esters (sucrose stearate) in concentration range of the surfactant from 0.01% to 10%, see column 2, lines 39-54. The reference teaches that the surfactant is safe are recognized safe and widely used in pharmaceutical and food industries and can be used alone or in mixture for obtaining the desired emulsifying properties, see column 2, lines 39-54 and 58-60 for amounts.

Shukuzaki et al. teaches oily make up cosmetic composition which provides excellent feeling upon use and superior make up effect and good stability over time comprising oil base and silicone gel composition comprising surfactants which are solid and have melting point of 40 degrees celsius or higher such as sucrose fatty acid esters, see claim 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize surfactant in a submicron emulsion formulation of Ribier as disclosed by teachings of Tabibi which discloses submicron emulsion with surface active agents. Motivated by the teachings of Schwartz et al. and Shukuzaki et al., it would have been further obvious to one of ordinary skill in the art at the time the

invention was made to incorporate surfactant such as sucrose stearate or sucrose fatty acid ester in the compositions of Ribier et al. in order to reduce surface tension because it was well known in the art to utilize such surfactant in cosmetic preparations. Utilization of well known surfactant in a cosmetic composition for better emulsifying properties would have been obvious to one of ordinary skill in the art at the time of instant invention with an expectation to obtain predictable results. Furthermore, generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. Regarding the ratio by weight of the amount of oily phase to the amount of surfactant as recited in instant claim 28, Ribier et al. teach the amount of oil ranges from 5 to 30% by weight with respect to the total weight of the emulsion (column 3, lines 16-18). Tabibi et al. teach submicron emulsions of adsorptive oils containing surfactants; it would be obvious to optimize the ratio of oily phase to surfactant by doing experimental manipulations in order to obtain best possible results absent evidence to contrary.

The references discussed above do not teach turbidity requirements claimed.

Halloran teaches optically clear shampoo compositions containing amino functional silicone micro emulsions, title. That reference teaches that the term "optically clear" is used to define a composition that is transparent (transmitting light without distortion) which means that the size of the particles in the composition are reduced to a size where they are not observable with optical (visual) means. According to this invention, "optically clear" is further defined by NTU's (Nephelometric Turbidity Units), which is the unit of measure for the **turbidity or haze of a liquid. NTU's** range from

**0.04 to 1,000 or higher.** A more detailed description of this test is found here in below.

The haze value of a relatively turbid solution is about 100 NTU's or higher, and mixtures with a slight haze give values of 20 to 50 NTU's. In contrast the compositions of this invention have an average haze value of 3 to 5 NTU's that is optically clear shampoo composition.

Based on Halloran's teachings, it is the position of the examiner that the prior art's nanoemulsion will exhibit substantially similar turbidity because the combination of Ribier and Tabibi make obvious the claimed nanoemulsion composition. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

4. Claims **25, 27-34 and 36-43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (US 5,753,241), in view of (Schwarz et al. (USP 6, 117,415) or Shukuzaki et al. (USP 5,266,321) or Tachibana et al. USP 5,412,004)) and as evidenced by Halloran (USP 6,153,569).

The teachings of Ribier have been cited above; the reference does not teach the specifically claimed surfactants such as esters of fatty acid and sugar as claimed.

Schwarz et al. teaches a submicron emulsion comprising surfactant such as sugar esters (sucrose stearate) in concentration range of the surfactant from 0.01% to 10%, see column 2, lines 39-54. The reference teaches that the surfactant is safe are recognized safe and widely used in pharmaceutical and food industries and can be used alone or in mixture for obtaining the desired emulsifying properties, see column 2, lines 39-54 and 58-60 for amounts.

Shukuzaki et al. teaches oily make up cosmetic composition which provides excellent feeling upon use and superior make up effect **and good stability** over time comprising oil base and silicone gel composition comprising surfactants which are solid and have melting point of 40 degrees celsius or higher such as sucrose fatty acid esters, see claim 1.

Tachibana et al. teaches silicone polymer and water/oil composition comprising surfactant such as sucrose fatty acid ester, see table 4 and Examples.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate surfactant such as sucrose stearate or sucrose fatty acid ester in the compositions of Ribier et al. in order to reduce surface tension and for better emulsifying properties because it was well known in the art to utilize such surfactant in cosmetic preparations. Utilization of well known surfactant in a cosmetic composition would have been obvious to one of ordinary skill in the art at the time of instant invention with an expectation to obtain predictable results. No unexpected results have been shown with the specifically claimed surfactants which are known in the cosmetic art. Furthermore, generally, it is *prima facie* obvious to select a known



material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. Regarding the ratio by weight of the amount of oily phase to the amount of surfactant as recited in instant claim 28, since Ribier et al. teach the amount of oil ranges from 5 to 30% by weight with respect to the total weight of the emulsion (column 3, lines 16-18) and Schwarz et al. teaches a submicron emulsion comprising surfactant such as sugar esters (sucrose stearate) in concentration range of the surfactant from 0.01% to 10%, in column 2, lines 39-54; it would be obvious to optimize the ratio of oily phase to surfactant by doing experimental manipulations in order to obtain best possible results absent evidence to contrary.

The references discussed above do not teach turbidity requirements claimed.

Halloran teaches optically clear shampoo compositions containing amino functional silicone micro emulsions, title. That reference teaches that the term "optically clear" is used to define a composition that is transparent (transmitting light without distortion) which means that the size of the particles in the composition are reduced to a size where they are not observable with optical (visual) means. According to this invention, "optically clear" is further defined by NTU's (Nephelometric Turbidity Units), which is the unit of measure for the turbidity or haze of a liquid. NTU's range from 0.04 to 1,000 or higher. A more detailed description of this test is found here in below. The haze value of a relatively turbid solution is about 100 NTU's or higher, and mixtures with a slight haze give values of 20 to 50 NTU's. In contrast the compositions of this invention have an average haze value of 3 to 5 NTU's that is optically clear shampoo composition.

Based on Halloran's teachings, it is the position of the examiner that the prior art's nanoemulsion will exhibit substantially similar turbidity because the combination of Ribier and references discussed above for utilizing surfactants such as sucrose stearate (sucrose fatty acid esters) and make obvious the claimed nanoemulsion composition.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

#### **Response to Arguments**

5. Applicant's arguments filed 12/21/10 have been fully considered but they are not persuasive.

Applicant argues that none of the applied art teaches or suggests adding the required solid surfactants to oil-in-water nanoemulsions having 10-40% oily phase comprising at least one oil having a molecular weight of greater than 400 and a turbidity of 60-600 NTU.

Applicants arguments are not persuasive because as discussed in the rejection above, Ribier teaches oil in water emulsion with 5 to 30% oil, thus the amount of oil overlaps with the claimed amount of oil in emulsion. Regarding the claimed surfactant Tabibi teaches uses of surfactant and Schwarz et al. teaches a submicron emulsion comprising surfactant such as sugar esters (sucrose stearate) in concentration range of

the surfactant from 0.01% to 10%, see column 2, lines 39-54. The reference teaches that the surfactant is safe are recognized safe and widely used in pharmaceutical and food industries and can be used alone or in mixture for obtaining the desired emulsifying properties, see column 2, lines 39-54 and 58-60 for amounts and the reference by Shukuzaki et al. as discussed in rejection above teaches oily make up cosmetic composition which provides excellent feeling upon use and superior make up effect **and good stability** over time comprising oil base and silicone gel composition comprising surfactants which are solid and have melting point of 40 degrees celsius or higher such as sucrose fatty acid esters, see claim and Tachibana et al. teaches silicone polymer and water/oil composition comprising surfactant such as sucrose fatty acid ester, see table 4 and Examples.

Therefore based on Halloran's analysis, one of ordinary skill would expect the properties of turbidity to be substantially similar to the claimed turbidity.

Applicant further argues that the previously-submitted Rule 132 declaration demonstrates that Comparative Composition A containing a liquid sugar surfactant was unstable after 1 month increased turbidity, particularly at increased temperatures. Also, after 2 months, the composition was completely unstable, making turbidity measurements impossible. In stark contrast, Invention Compositions B and C containing solid sugar surfactant were stable, even after 2 months, and these compositions had low and stable turbidity characteristics, even at increased temperatures. This vast difference in physical properties among Comparative Composition A and Invention Compositions B and C was surprising and unexpected

given the similarity of the compositions (the only noticeable difference being the use of a solid sugar surfactant as opposed to a liquid sugar surfactant). Thus, the benefits associated with the claimed invention requiring the presence of a solid sugar surfactant are unexpected and surprising, and could not have been suggested by the remaining applied art.

Applicant arguments are not persuasive because first utilization of the claimed surfactants has been shown to be used for emulsifying properties and stability by the prior art discussed in the rejection above. Additionally, the declaration comprises 4.5% of specific surfactant such as sucrose palmitostearate where as the claims as recited read on any surfactant that is solid at a temperature of 45 degrees Celsius which includes innumerable list of surfactants, as such the declaration is not commensurate with the scope of the claims. The claims are very broad in scope. Second, the limitation of surfactant being solid at temperature less than or equal to 45 degrees Celsius reads on any surfactant which has melting point of less than 45 degree Celsius such is not the case as per the disclosure. The disclosure does not support such surfactants. Applicant has only substantiated the results with specific surfactant, as such the claims do not commensurate with the scope of declaration. Applicant has provided comparison of results with only one of the examples from Ribier, however, Ribier teaches multiple examples; see columns 5 and 6 of Ribier. Comparison does not call for picking and choosing from prior art, it is rather comparison of the whole prior art versus the claimed invention. The claimed amount of surfactant in claim 27 is from 0.2 to 15%; however, the declaration only provides data with 4.5%. As such no effect of

surfactant has been shown for the lower limits. As such the declaration is insufficient to overcome the rejections.

**6. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore /

Primary Examiner, Art Unit 1612